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09/937,313	09/24/2001	Gunther Berndt	0050/49860	8414

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT PAPER NUMBER

1615

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,313

Applicant(s)

BERNDL ET AL.

Examiner

Micah-Paul Young

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-12 and 14-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-12 and 14-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1615

DETAILED ACTION

Acknowledgment of Papers Received: Request for Continued Examination dated 10/15/04.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 10-12-14,17,19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Guzi, Jr. et al (USPN 4,127,422 hereafter '422). The claims are drawn to a process for making an excipient comprising spray-drying a solution comprising a water-soluble N-vinylpyrrolidone polymer and a surface active agent.

4. The '422 patent discloses a process for making dry polymer compound comprising polymer of N-vinyl pyrrolidone and a surfactant (abstract, col. 3, lin. 5-15), where a solution comprising the polymers is spray-dried (claim 2). The surfactant can be nonionic and can have ab HLB from 11-18 (col. 3, lin. 10-11, lin. 33-42). The N-vinyl pyrrolidone has a K value between 15 and 21 (example 7). The formulation further comprises other polymers such as

Art Unit: 1615

starches, gums, and cellulose derivatives, all of which are useful as flow regulator agents, bulking agents and tableting excipients (col. 5, lin. 9-19). The formulation also comprises a pigment (examples).

5. Regarding the limitations of claims 14 and 17, reciting the specific concentrations of surfactant in the excipient, it is the position of the examiner that such limitations do not impart patentability in view of the prior art. '422 discloses a process for making an excipient comprising polyvinylpyrrolidone, and a surfactant, where the solution is spray-dried. The general conditions of the limitations are met by these disclosures. It is the position of the examiner that the determination of these ranges is well within the level of ordinary skill in the art and can be determined through routine experimentation. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

6. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

7. Regarding claim 11, it is the position of the examiner the drop point would be inherent to any surfactant with the appropriate HLB and solubility. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and

Art Unit: 1615

functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

8. With these things in mind it would have been obvious to follow the suggestions of the '422 reference to produce a dry excipient comprising a vinylpyrrolidone polymer and a nonionic surface-active agent by spray drying. A skilled artisan would have been motivated to optimize the concentrations and ranges of the reference in order to provide a superior excipient product. It would have been obvious to skilled artisan to follow these teachings with an expected result of a spray-dried excipient with improved stability.

9. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Guzi, Jr. et al (USPN 4,127,422 hereafter '422) and Shih et al (USPN 6,011,096 hereafter '096); and Sutton et al (USPN 5,993,805 hereafter '805). The claims are drawn to a process for making an excipient comprising spray drying a solution comprising a water-soluble N-vinylpyrrolidone polymer and a surface-active agent.

10. As discussed above the '422 reference discloses a process for making an excipient comprising a polymer of N-vinylpyrrolidone and a surface active agent, where a solution of the polymers is spray-dried. The reference discloses such surfactants as oleates and polyether alcohols (col. 3, lin. 10-35), yet is silent to the specific surfactant of claim 15. However the

Art Unit: 1615

inclusion of specific components that have an established equivalency is well within the level of skill in the art, as seen in the '096 reference.

11. The '096 patent discloses a composition comprising polyvinylpyrrolidone with a K value between 12 to 120 and emulsifier surfactants such as lauryl alcohol polyether, oleates and polyethoxylated sorbitan (col. 2, lin. 12-20, col. 3, lin. 8). The small particles recovered from the suspension are of a higher purity (col. 2, lin. 38-46). A skilled artisan would have been motivated to combine the surfactant of '096 into the formulation and process of '422 since they both combine water-soluble emulsifiers.

12. The '422 reference further suggests the inclusion of polyoxyethylene fatty glycerides and polyethylene glycol, yet is silent to the inclusion of the specific surfactant of claim 16. However the inclusion of specific components that have an established equivalency is well within the level of skill in the art, as seen in the '805 reference.

13. The '805 patent discloses a spray-dried microparticle formulation comprising water-soluble hydrophilic compounds such as polyvinylpyrrolidone (col. 7, lin. 44), and surface-active agents such as glycerol polyoxyethylene rinoate, polyoxypropylene glycol and polyoxyethylene glycol (col. 7, lin. 58-63). These compounds are similar to those of the '422 and would be within the level of skill in the art to substitute into that formulation.

14. With these things in mind it would have been obvious to a skilled artisan to combine the teachings and suggestions of the art. A skilled artisan would have been motivated to combine the surfactants of '096 into the process of '422, under its suggestions to improve the purity and stability. A skilled artisan would have been motivated to include the combine the surfactant of '805 into the process of '422, under its suggestions in order to improve the stability of the

Art Unit: 1615

formulation. It would have been obvious to a skilled artisan to combine the teachings and suggestions as such with an expected result of a spray-dried excipient with improved stability and purity.

15. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Guzi, Jr. et al (USPN 4,127,422 hereafter '422). The claims are drawn to a process for making an excipient comprising spray drying a solution comprising a water-soluble N-vinylpyrrolidone polymer and a surface-active agent.

16. As discussed above the '422 reference discloses a process for making an excipient comprising a polymer of N-vinylpyrrolidone and a surface active agent, where a solution of the polymers is spray-dried. The reference however is silent to the particular particle size of the excipient. The reference suggests that the particle size must be manageable enough to avoid agglomeration (col. 3, lin. 52-68).

17. The '769 reference discloses a composition comprising water-soluble polyvinyl pyrrolidone with a K value from 70 to 100 (col. 2, lin. 11-20). The composition can be processed by various means, including spray drying where the resultant particles are in the range 25 to 700 microns (claims). A skilled artisan would be motivated to include the composition because of its improved flow properties eliminating agglomeration.

18. With these things in mind a skilled artisan would have been motivated to include the PVP composition of '769 into the process of '422 in order to improve the flow of the excipient and reduce agglomeration. It would have been obvious to combine these teachings with an expected result of a spray-dried excipient with improved flow and agglomeration properties.

Art Unit: 1615

Response to Arguments

19. Applicant's arguments with respect to claims 10-12, and 14-20 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MP Young

Micah-Paul Young
Examiner
Art Unit 1615


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